Department of Health and Human Services National Institutes of Health Agency Agreement and Clearance Intra-agency Agreement (within NIH)				Paying Agency Agreement Number (including Mod. No.) Y1-HD-6001-01					
☐ Intra-agency Agreement (within NIH) ☐ Inter-agency Agreement (outside NIH)			111 11	2. Receiving Agency Agreement Number (including Mod. No.) CPSC-I-06-0015					
4. Title of Agreement Study of Injuries Amo				ng Children with Developmental Disabilities					
The primary g	oal of t	his study is t	o describe the	epidemiology of	of injuries amo	ong children with	quipment, facilities, etc.) disabilities. This will be n in Emergency Depar		
(31 USC 1535 a Title 7, Sections SECTION (c.) a				is made under the authority of the Economy Act, approved June 1932 as amended and 1536) and under the provision of the GAO Policy and Procedures Manual, 8.4 and 13.2(1) and the Consumer Product Safety Act of 1973, 15 U.S.C. 2068(c) and (e)					
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Receiving Agency 11. Agency Lot 61000001 CPSC 12. Employee DUNS - 0692 EIN - 52-097		e Identification N 287522	lumber & DUNS	· 					
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14. Paying Federal Agency	15. Agre	ement No. modification for NIH Y1/Y2)	16. Appropriation	17. CAN	18. Amount	19. Signatories	(Name and Title)	20. Date	
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						Donna Hutton Contracting Off	cer, CPSC_	 	
Agency Clearances———Paying Agency Clearances———Paying Agency Clearances————————————————————————————————————				Date	Name and Title	Agency Clearances-	Receiving Agency	Date	
Gitanjali Saluja, Ph.D. DESPR, NICHD Gotanti S		48	6/23/2006						
Budget Office Bldg. 31/2A47		giphondros		7/12/2006					
Dexter Collins, Acting Asset Dir. Adm. NICHD			7/7/2006						
Yvonne Maddox, Ph.D. Deputy Dir., NICHD		J. Mule	0 2/13/00						
NIH 1742 (Rev. 1/03 by NICHD) Use prescribed by NIH Manual 1165									

INTERAGENCY AGREEMENT BETWEEN

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT Y1-HD-6001-01 and THE UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION

TITLE: Study of Injuries Among Children with Developmental Disabilities

I. BACKGROUND and PURPOSE:

Injuries among typically developing children have been recognized as a public health problem for many years and the epidemiology of childhood injuries is well studied. In contrast, injuries among children with physical and intellectual disabilities have been highly overlooked. This is particularly true for unintentional injuries, the leading cause of death among children in the U.S. and other developed countries. For example, motor vehicle related injuries are the leading cause of death among all children in the U.S. and falls are the leading cause of non-fatal injury, accounting for over 2 million emergency room visits per year. Comparable figures for the disabled population are virtually absent. Because of this lack of data, it has been difficult for physicians and other health professionals to counsel parents on injury-risks that are particularly relevant for their children.

The proposed study makes use of the National Electronic Injury Surveillance System, which is part of the routine data collection of the Consumer Product Safety Commission. In the NEISS hospitals, trained abstractors code information from all injury-related emergency department visits in the participating hospital. Variables that are part of this collection include age and gender of victim, injury diagnosis (e.g. laceration, burn), body parts affected, external cause of injury (e.g. fall, car crash), and incident locale. Each record also contains a brief narrative description of the injury incident. Underlying disabilities are not currently coded. The primary goal of this study is to determine if children with disabilities are at increased risk of injury and second to identify which injuries they are at particular risk of sustaining. NICHD proposes to collect information about disabilities among children with injuries through phone interviews with cases identified during the routine data collection of the NEISS. NICHD also proposes to collect data on other potential risk factors for injury including family structure, sibling characteristics, and caregiver supervision practices. Finally, NICHD would like to determine if typically developing children who have a sibling with a developmental disability, who may compete for supervisory time, are at a greater risk of injury than other children.

II. Statement of Work

This Agreement provides funds from NICHD to CPSC to complete 8000 follow-up interviews with parents/guardians of injured children. The sample of interviewees will be derived from a larger sample of injured children who will be systematically selected from the NEISS system. Sampling will cover an entire year to account for seasonal variations in injury rates. Two thousand interviews will be conducted in 4 different age groups: 0-4 years; 5-9 years, 10-14 years, and 15-19 years. Cases will have a mechanism of injury code indicative of an unintentional injury. Intentional injuries will not be included in the sampling pool. Further, deaths and hospitalizations will be excluded. Interviews will be limited to those who can complete an interview in English or Spanish.

NICHD will provide CPSC with a questionnaire containing items on developmental disabilities and other potential risk factors for injury. CPSC staff will work with NICHD staff to finalize the questionnaire. As

part of this process CPSC will pilot test the questionnaire with staff to ensure that all questions are clear and all skip patterns work properly. As part of the questionnaire development, cognitive interviews will take place with parents, to ensure that the content of the questionnaire is properly understood. The interview will be designed to be less than 25 minutes. Interviewers will take required short course on IRB/Human Subjects regulations as specified by NICHD.

CPSC staff will conduct telephone interviews within two weeks of the child's visit to the Emergency Room, minimizing recall bias about the injury event. Interviews will be conducted by trained staff and interviews will be done using Computer Assisted Telephone Interviewing (CATI). CATI Interviewers will possess basic interviewing knowledge and skills; however they will receive additional instruction from NICHD on the content of this specific interview. Interviewees will be asked to give verbal consent over the phone to be interviewed. Parents and guardians will be asked specific questions about whether or not their children (both the child that was injured and his/her siblings) have a developmental disability. To allow comparisons to national data, a general question about disabilities will be asked using the exact wording used in the National Health Interview Survey. Separate questions will be asked to ascertain the presence of specific disabilities. Additional questions on child characteristics and family composition will be included as well.

NICHD will work jointly with CPSC to obtain appropriate IRB and OMB approval for this study.

III. REPORTING REQUIREMENTS

CPSC will send NICHD PDF files of the completed interviews and a SAS data set with the questionnaire data linked to the NEISS data. For the first month of the study, PDF files will be sent weekly. After the first month of data collection, CPSC will send PDF files and an updated SAS dataset on a monthly basis.

IV. ADVANCE UNDERSTANDINGS

One or more publications will result from this project. Lead authorship will be taken by Drs. Saluja and Brenner from NICHD. Tom Schroeder (U.S. Consumer Product Safety Commission) and possibly other personnel will be co-authors.

V. PERIOD OF PERFORMANCE

The Period of Performance for this project is <u>1 April 2006</u> through <u>31 October 2007</u>. This agreement may be modified by mutual consent of both parties.

VI. AUTHORITY:

This agreement is made under the authority of the Economy Act, approved June 30, 1932 (31USC 1535 and 1536) and under provision of the GAO Policy and Procedures Manual, Title 7 Sections 8.4 and 13.2(1) and the Consumer Product Safety Act and the Consumer Product Safety Act of 1973, 15 U.S.C. 2068(c) and (e).

VII. COST/METHOD OF PAYMENT

The estimated cost for telephone call back is \$90 per expected completed case. This lump sum includes the cost to select the sample, develop a Computer Assisted Telephone Interview (CATI) questionnaire, administer the questionnaire, collect the data, process the data, and produce an analysis file that contains both the data routinely collected in NEISS and the data collected for this special study. It is anticipated that eight thousand interviews will be conducted. To cover the cost, NICHD is

providing \$320,000 in FY 2006; and depending upon the availability of funds the the research needs of the NIHCD, \$400,000 will be funded in FY 2007 for a total cost of \$720,000.00.

Billing will be accomplshed via the Simplified Intergovernmental Billing and Collection (SIBAC) system for the amount of \$320,000.00 in FY 2006.

VIII. FUNDING

All funds provided by NICHD in this agreement must be obligated by the performing agency by the end of the fiscal year in which the funds expire. Any unobligated but expired funds may not be used to fund services in subsequent periods. NICHD must be notified of any unobligated funds pertaining to this agreement at least 15 days before the end of the fiscal year so that the agreement can be amended to reduce the obligated amount when appropriate.

IX. ACCOUNTING/BILLING INFORMATION

Funds for this project for FY 06 in the amount of \$320,000.00 will be transferred to CPSC from NIH/NICHD

FROM TO **CPSC NICHD** Agency Agency Location Code: 75-08-0031 61000001 Appropriation: 75-06-0844 6160100 CAN: 6-8421373 Accounting Trip:

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X. LIAISONS

The Project Officers of the two Agencies represented in the Agreement are:

NICHD

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The Administrative/Budget Contacts are:

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Phone: 301-435-6962 FAX: 301-402-3676

a.	SIGNATURES and/or APPROVED AND ACCEPTED FOR:				
	NIH/NICHD	CPSC			
L	Dyane Alexander, M.D., Director	Donha Hutton, Contracting Officer CPSC			
O' Ē	7/18/06 DATE	8/10/06 DATE /			